

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-307

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

CLINICAL PHARMACOLOGY REVIEW

NDA:	22-307	N000
Submission Dates:	12/27 2007, 2/4 2/19 2/25, 2/28 3/20, 4/28, 5/9 5/12 2008	
Brand Name:	Effient	
Generic Name:	Prasugrel Hydrochloride	
Dosage Form & Strength:	Tablets 5 mg and 10 mg	
Indication:	Reduction of atherothrombotic events and stent thrombosis in ACS patients with stable angina or NSTEMI	
Applicant:	Eli Lilly, Inc.	
Submission:	Original NDA	
Divisions:	DPEI and Cardio-Renal Drug Products, HFD-110	
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